REMARKS

Claims 40, 44-61 and 63-64 were pending in the application. Claims 44 and 58-60 are amended and claims 65-66 are added. Set forth above is a detailed listing of all claims, with appropriate status identifiers, that are or were pending in the application. Upon entry of the foregoing amendments, claims 40, 44-61 and 63-66 will be pending. Reconsideration of those claims is respectfully requested.

Examiner Interview

Applicant thanks Supervisory Examiner Thurman Page for the courtesies extended to Applicant's representative during the interview conducted on May 13, 2004. Applicant believes that the interview was helpful in advancing prosecution of the application. The substance of the interview, which also is reflected in the Interview Summary, is summarized below with reference to the specific issues discussed at the interview, including proposed claim amendments, the pending §112 rejection, the pending prior art rejection, and other issues.

Claim Amendments

The amendments set forth above are largely clerical in nature and address the examiner's objections and rejections. Specifically, claim 44 is amended to clarify that the claimed drug delivery system is non-occlusive. This amendment does not narrow the scope of the claims because original claim 44 recited a non-occlusive drug delivery system. Claims 58-60 are amended to recite in separate claims (i) methods of treatment and (ii) methods of administering physiologically active agents or pro-drugs thereof to subjects at risk of developing certain conditions. These amendments do not narrow the scope of the claims because the claimed subject matter as a whole remains largely unchanged. Claims 65 and 66 are added to recite specific embodiments previously recited in claims 59 and 60. All of these amendments are fully supported by the application as filed and do not introduce new matter. Moreover, they were discussed during the interview. Entry of the amendments and reconsideration of the amended claims is respectfully requested.

The March 17, 2004 Office Action

The Office Action issued March 17, 2004, rejected claims 58-60 under 35 USC § 112 and rejected claims 44-46, 51, 57, 61 and 63 under §103. These rejections were discussed at the interview and are addressed in turn below.

1. The § 112 Rejection

Claims 58-60 were rejected for alleged lack of enablement with respect to prophylaxis. Specifically, the Action asserts that the specification does "not show how to prevent certain diseases." Applicant respectfully traverses this rejection.

At the outset, Applicant emphasizes that the present invention is not directed to a new drug that is able to prevent a condition that previously could not be prevented. Instead, the present invention is directed to a new drug delivery system that is able to deliver physiologically active agents and pro-drugs thereof. The specification teaches a number of conditions that are known to be preventable by the administration of physiologically active agents, and also sets forth a number of physiologically active agents useful in preventive methods. While the invention is not limited to the delivery of currently approved agents, the fact that such agents are approved and in use supports the enablement of this aspect of the invention. Those skilled in the art readily can apply the teachings in the specification regarding the novel drug delivery system to known preventive physiologically active agents and pro-drugs, and can practice the prophylactic methods without any undue experimentation.

This rejection was discussed during the interview, and Supervisory Examiner Page suggested that Applicant amend the claims to recite therapeutic methods separately from prophylactic methods, and that Applicant present claims to methods of administering physiologically active agents and pro-drugs to patients at risk of developing certain conditions. In accordance with these suggestions, Applicant has amended claims 58 and 59 to recite therapeutic methods only, and has amended claim 60 to depend from claim 57, which recites a method of administering a physiologically active agent or prodrug thereof, and to recite administration to an animal suffering from or at risk of developing acne, jetlag, asthma or nocturnal asthma. As discussed at the interview and demonstrated by the attached documents, physiologically active agents and prodrugs for the prevention of these conditions are known. Claim 63 has been added to recite the contraception embodiment. As discussed at the interview and demonstrated by the attached documents, physiologically active agents and prodrugs for contraception are known.

The information of record demonstrates that those skilled in the art will be able to practice the methods recited in claims 58-60 without an undue amount of experimentation. Applicant therefore respectfully urges that this rejection be reconsidered and withdrawn.

2. The § 103 Rejection

Claims 44-46, 51, 57, 61 and 63 were rejected under §103 as being obvious in view of U.S. Patent No. 5,082,656. Applicant respectfully traverses this rejection for the reasons set forth below.

The '656 patent is directed to a topical antibacterial composition. As taught throughout the patent, the composition "forms a water and wear resistant film" on the skin. This is in sharp contrast to the present invention, which provides a non-occlusive drug delivery system. As defined in the instant specification, the term "non-occlusive" refers to "not trapping or closing the skin to the atmosphere." The composition of the '656 patent does not meet this definition because it forms a water-resistant film on the skin. Moreover, there is no disclosure in the '656 patent that suggests a non-occlusive delivery system, such as the claimed delivery system.

This issue was discussed during the interview, and Supervisory Examiner Page suggested that Applicant amend the claims to clarify that the claimed delivery system is non-occlusive. While Applicant believes that the previous claims plainly recited non-occlusive delivery systems, Applicant has amended independent claim 44 to clarify that the claimed delivery systems are non-occlusive.

Applicant believes that these arguments and the clarification of claim 44 overcomes the § 103 rejection, and respectfully urges reconsideration and withdrawal of the same.

Other Issues Raised During the Interview

During the interview, Supervisory Examiner Page questioned whether the claims should be amended to recite that the drug delivery system comprises the dermal penetration enhancers set forth in claim 48, instead of reciting dermal penetration enhancers generally. Applicant respectfully responds that such an amendment would unduly and unnecessarily limit the scope of the present invention.

Although the dermal penetration enhancers set forth in claim 48 constitute one aspect of the present invention, the invention is not limited to drug delivery systems comprising such penetration enhancers. As set forth in claim 44, the present invention lies in a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising:

(i) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof;

(ii) at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(iii) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

where the dermal penetration enhancer (A) is adapted to transport the physiologically active agent across a dermal surface or mucosal membrane of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface or membrane, and (B) is of low toxicity to, and is tolerated by, the dermal surface or mucosal membrane of the animal;

and, where, after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry within 3 minutes of application.

This invention is not limited to a specific class of dermal penetration enhancers.

The specification plainly teaches that any known dermal penetration enhancer can be used in the drug delivery system of the present invention. *See, e.g.*, specification at page 18, line 21. The paragraph bridging pages 18-19 of the specification sets forth an exemplary list of suitable dermal penetration enhancers, and includes dermal penetration enhancers that are different from those recited in claim 48. That the invention is not limited to the dermal penetration enhancers of claim 48 is further supported by the Examples, which show effective transdermal delivery using transdermal drug delivery systems of the present invention comprising other dermal penetration enhancers, including Azone (*see, e.g.*, Table 1 at page 33, Table 3 at page 35, Table 6 at page 37, Table 10 at page 41, and Table 11 at page 43) and oleic acid (*see, e.g.*, Table 10 at page 41).

Applicant also draws the Examiner's attention to pages 24-25 of the specification, which explain the mechanism by which the drug delivery system is believed to provide effective transdermal delivery. While not being bound by this theory, Applicant notes that these teachings explain how the invention may work with any dermal penetration enhancer, and is not limited to drug delivery systems comprising the dermal penetration enhancers recited in claim 48.

In summary, the specification plainly teaches that the invention encompasses drug delivery systems comprising any dermal penetration enhancer and fully describes and enables that aspect of the invention. It therefore would be improper to limit the scope of the claims to the specific class of dermal penetration enhancers recited in claim 48.

Conclusion

In view of the foregoing, Applicant believe that the application is in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions regarding this submission, or should any issues remain, the Examiner is invited to contact the undersigned by telephone.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 CFR §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 8, 2004

By _____

Courtenay C. Brinckerhoff
Registration No. 37,288

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399